

REMARKS

The Office Action mailed April 19, 2007, has been carefully considered. Claims 1-3, 8 and 22 have been amended to more particularly point out and claim the instant invention. Applicants respectfully assert that the above changes to the claims introduce no new matter and Applicants respectfully submit that the application is in condition for allowance. Accordingly, reconsideration and withdrawal of the Rejection and issuance of a Notice of Allowance are respectfully solicited.

In the previous Office Action, the Examiner rejected claims 1-42. The arguments filed November 22, 2006 with respect to claims 1-42 were considered and the rejection of August 23, 2006 was been withdrawn. A restriction requirement was subsequently made and claims 9-14 and 23-42 were withdrawn from consideration. Claims 1-8 and 15-22 are once again submitted for consideration.

Claims 1-8 and 15-22 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. With respect to the first portion of the rejection, namely that connection of the electrodes should include "adapted to be located," Applicants respectfully traverse that portion, because claims 1 and 15 already contain such language. Claim 1, for example, recites that the at least two pairs of implantable electrodes are "adapted to be located at predetermined locations proximate to a subject's spinal cord." Applicants respectfully seek clarification from the Examiner because it appears that the first portion of the rejection is moot.

With respect to the rest of the rejection under 35 U.S.C. § 112, second paragraph, Applicants have made minor changes to the claims to address those rejections. Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

Claims 1-8 and 15-22 were rejected under 35 U.S.C. § 103(a) as being unpatentable over *King et al.* (U.S. Patent No. 6,505,078) in view of *Carter et al.* (U.S. Patent Publication 2001/0031999). Applicants respectfully traverse this rejection according to the remarks that follow.

The present invention, according to claim 1, is directed to an electrical stimulator for the treatment of intractable pain syndromes, which includes an interferential current generator having common sine wave generators which generate an interferential alternating current output. It further includes the generation of a sine-wave-like output waveform having first and second sinusoidal signals having different first and second frequencies, with a base medium frequency of at least 500Hz but no more than 20KHz. The stimulator also includes at least two pairs of implantable electrodes connected to the interferential current generator and adapted to be located at predetermined locations proximate to a subject's spinal cord wherein each pair of the at least two pairs of implantable electrodes produces a separate electrical circuit, each transmitting one of the first and second sinusoidal signals, such that the first and second frequencies interfere with each other to produce at least one beat frequency signal proximate to the subject's spinal cord. Claim 15 recites a similar electrical stimulator without the specific recitation of common sine wave generators.

King et al. is directed to an apparatus where first and second pulses are applied to first and second electrodes, respectively, to generate first and second subthreshold potential areas, respectively, within the tissue. The locus within the tissue where action potentials are induced is determined by a superposition of the first and second subthreshold areas according to the physiological principle of electrotonus. The cathode may be positioned near the center of the two-dimensional array or may be left out.

King et al. works with pulses that are separated in time, as shown in Fig. 12, and have areas of excitation that overlap. That applies more energy per unit time to the overlap (15A)

to cause a greater intensity effect. Applicants also note that the reference fails to disclose the use of any beat frequencies in the application of the fields to the tissue.

Carter et al. is directed to an electro-therapy apparatus and method for providing therapeutic electric current to a treatment site of a patient, having means for providing two oscillating or pulsing electric alternating currents of frequencies which differ from each other by as little as 1 Hz and up to about 250 Hz, but each being of frequency of at least about 1 KHz. The apparatus and method requires only one large feed electrode adapted to feed the electric currents to selected feed sites on or beneath the epidermal or mucous surface of the patient, and only one small return electrode adapted to be positioned on or beneath the epidermal or mucous surface of the patient, locally to the treatment site. The effect in *Carter et al.* is to cause fast firing within the refractory period of the nerve, as shown in Fig. 1, so that no pain impulses or any type of impulses are carried on the nerve.

Applicants respectfully traverse this rejection because the combined references fail to teach the subject matter of claims 1 and 15 and the motivation supplied to the combination in the rejection is insufficient to make out a *prima facie* case of obviousness. It is not clear how the benefits described in *King et al.* would be maintained if the references were combined. In *King et al.*, the time difference in the pulses produces the subthreshold areas. It is not clear how the application of a beat frequency would achieve the benefits described. In *King et al.*, the areas around the region would be bathed in energy, but not with the increased depth and amplitude caused by the beat frequency of the present invention. In fact, production of actual beat frequencies would not occur with pulses that are separated in time, as described in *King et al.*

In addition, it is also not clear how the preference in *Carter et al.* of having a single source electrode and a single return electrode would be accommodated in *King et al.*, where multiple feed electrodes are being employed. The motivation to combine the references is

insufficient since the frequency range specified in the rejection, i.e. 500Hz to 20KHz, is nowhere found specifically disclosed in either reference. The motivation to combine the references is also insufficient because the "benefit" of the combination, i.e. "providing optimal therapeutic benefits for pain suppression," can be met by either *King et al.* or *Carter et al.* alone. Without more, the Office has simply placed the references together because the Office can and the motivation can only be improper hindsight reasoning because no other source but Applicant's disclosure would motivate the combination.

Additionally, given the disclosure of *King et al.*, one of ordinary skill in the art would not have been motivated to reach the subject matter of the present invention. As discussed in the background of *King et al.*, the electrodes often need to be placed optimal positions in order to "steer" the electric fields. Because the instant invention is concerned with interferential stimulations, which present deeper into the body of the patient, the placement of the electrodes does not create a similar issue. As such, for this additional reason, one of ordinary skill in the art would not look to *King et al.* or *Carter et al.* to reach the subject matter of the present invention.

Also, the 'beat frequency' in *Carter et al.* is not interferential, as recited in the independent claims. Claim 1, for example, recites that each of the sinusoidal signals is transmitted "such that the first and second frequencies interfere with each other to produce at least one beat frequency signal." The signal in *Carter et al.* is introduced to the body and the signal is "multiplied by materials in the body" to give rise to signals having different frequencies. Such methods provide much less control than the present invention such that precise signals of a specific frequency may not be obtained.

In addition, the *King et al.* or *Carter et al.* references work very differently and employ different methods. *King et al.* is concerned with creating overlapping regions to achieve an overall greater period of application and *Carter et al.* is concerned with inhibition

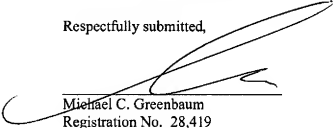
of pain through high frequency signals. One of ordinary skill in the art would not have been motivated to combine the *King et al.* and *Carter et al.* references because they are very different and could not readily be combined. As discussed above, even if they were somehow combined, Applicants respectfully assert that they would not result in the subject matter of the present invention.

For at least those reasons, Applicants respectfully traverse the rejection of claims 1 and 15. The rejection of claims 2-8 and 16-22 is also traversed for at least the reason that such claims are dependent on independent claims 1 and 15.

In the event there are any questions relating to this Response or to the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney concerning such questions so that the prosecution of this application may be expedited.

Please charge any shortage or credit any overpayment of fees to BLANK ROME LLP, Deposit Account No. 23-2185 (000309-00053). Any fees due are authorized above.

Respectfully submitted,



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